



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/125,814	08/26/98	DOHI	851585

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WASHINGTON DC 20037

EXAMINER BERMAN, A

ART UNIT 1615	PAPER NUMBER 9
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DATE MAILED: 08/24/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/125,814

Applicant(s)

Dohi et al.

Examiner

Alysia Berman

Group Art Unit

1615



☒ Responsive to communication(s) filed on Jul 12, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 19-32, 34, and 36-45 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 19-32, 34, and 36-45 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Receipt is acknowledged of the Request for Extension of Time and Amendment filed 21 July 1999. Claims 33 and 35 are canceled. Claims 19-34 and 36-45 are pending.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Applicants indicated in the Amendment filed 21 July 1999 that a substitute abstract was attached. No abstract was found with the Amendment.

Claim Objections

3. Claim 45 is objected to because of the following informalities: the word, "in," was left out of the phrase, "described claim 41" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 19 recites the limitation "the water-**soluble** and gel-forming base" in line 12. There is insufficient antecedent basis for this limitation in the claim. It is assumed that this is referring back to "a water-**absorbing** and gel-forming base" in line 4. All terms and description should be kept consistent to avoid any potential for indefiniteness.
7. Regarding claims 19, 24 and 25, it is unclear what Applicant contemplates by using the terms water-insoluble and water-soluble. Some of the compounds listed as water-insoluble are water-soluble, such as gelatin. Clarification is requested.
8. The term "on/in" renders the claims indefinite. It is unclear how the drug can be dispersed on and in the bases. The addition of a drug dissolved in water to a water-absorbing material would result in the solubilized drug being absorbed into the water-absorbing material.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 19-26, 28-32, 34 and 36-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Suzuki et al. (US 4613500).

See paper no. 5. For crystalline cellulose, see column 4, lines 21-22. For hydroxypropyl cellulose, see column 5, line 15. Properties which are inherent to a compound, such as the

viscosity of hydroxypropyl cellulose as instantly claimed in claim 27, are not patentable over the prior art disclosure of the compound.

As stated in paper no. 5, a product obtained by a particular process is not considered patentable over the prior art product. See *In re Masosi*, 710 F.2d, 218 USPQ 289 and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964. Further, by Applicant's own admission, the product may be obtained by any one of several processes, such as different particle sizes, lyophilization and mechanical mixing.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 19-32, 34 and 36-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. as applied to claim 19 above in further view of Makino et al. (US 5262871).

See paper no. 5.

Response to Arguments

13. Applicant's arguments filed 21 July 1999 have been fully considered but they are not persuasive.

14. Applicant argues that Suzuki does not teach the drug unevenly dispersed on/in the water-absorbing and water-insoluble base. Applicant further argues that Suzuki teaches that the drug is evenly dispersed on/in both the water-absorbing and water-insoluble and the water-absorbing and gel-forming bases.

The polypeptide of Suzuki is dissolved in water. With addition of a solution of the active agent in solubilized form, it is common knowledge that the solution containing the drug will be absorbed more in one base than the other because of the absorption differences of the bases. The instant claims do not recite any percentages of the drug on either of the bases to distinguish them from the prior art.

15. Applicant argues that the amount of 5-40 wt. % of the water-soluble and gel-forming base in relation to the total weight of the base materials is crucial to the invention.

Suzuki teaches the amount of the water-absorbing and gel-forming base should be between 0.1 to 60 wt.% based on the weight of the water-absorbing and water-insoluble base. In example 1 in column 7, 3600 mg of crystalline cellulose is used to make the powdery composition. The addition of a water-absorbing and gel-forming base at 20% of the amount of crystalline cellulose would result in the water-absorbing and gel-forming base making up about 16% of the total weight of the bases combined. Therefore, this encompasses the invention as instantly claimed.

Presently, no claim is allowed.

Application/Control Number: 09/125814
Dohi et al.
Art Unit: 1615

Page 6

Correspondence

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is (703) 308-4638. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234 or 1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



Alysia Berman
Patent Examiner
August 16, 1999